**TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY**

**APPLICATION FORM FOR RENEWAL OF A REGISTERED MEDICAL DEVICE INCLUDING IN VITRO DIAGNOSTIC DEVICE**

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|---|---|
| Brand name: | |
| Generic name: | |
| Registration number: | |
| Risk Class: | |
| GMDN Code: | |
| GMDN Category: | |
| Model /Series/System (***if applicable***) | |
| Packing/pack size ***(if applicable)*** | |
| Name and address (physical and postal) of Applicant (Must be the holder of the marketing authorization/registration certificate) | |
| Name and address (es) of the manufacturer(s) of the IVDD. *(Add as many rows as necessary)* | |
| Name and address of the manufacturing site | |
| Name and complete address of the Local Responsible Person (*who must be resident in Tanzania and in case of company be incorporated in Tanzania)* | |
| Detailed device description (Additional information can be attached with this form) | |
| Is there any change(s) to the device / | |

| | |
|---|---|
| manufacturing process (Yes/ No)<br><br>If Yes, please provide details for the change(s) made. If change(s) is/are major apply for new registration | |
| Other Application(s) (*Please provide brief information on any ongoing variation variation(s) submitted in parallel with renewal application(s) or line-extension*(s)) | |

Declaration of the Applicant:

I hereby submit an application for the above Marketing Authorization to be renewed in accordance to conditions given above.
I declare that (*Please tick the appropriate declarations*):

There are no other changes than those identified in this application (except for those addressed in other variations submitted in parallel; such parallel variations have to be specified under 'Other Application(s)');

Where applicable, registration fees have been paid; Name:

Name: _____

Qualification:_____

Position in the company: _____

Signature:_____

Date:_____

Official stamp: